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Bayer AG v. Housey Pharmaceuticals Inc., 68 USPQ2d 1001 (CA FC 2003)

68 USPQ2D 1001
Bayer AG v. Housey Pharmaceuticals Inc.

U.S. Court of Appeals Federal Circuit

No. 02-1598
Decided August 22, 2003

Headnotes

PATENTS

[1] Infringement — In general (§120.01)

International issues — In general (§157.01)

Patent infringement liability under 35 U.S.C. §271(g) is limited to importation of physical articles that have been "manufactured," and statute therefore does not apply to importation of information produced abroad, since language of Section 271(g) imposes liability for importing "a product which is made by a patented process," since related patent law provisions, and legislative history of Process Patents Act, support conclusion that "made"means "manufactured," and since reading statute to cover processes other than manufacturing processes could lead to anomalous results, in that person possessing allegedly infringing information could possibly infringe merely by entering United States.

[2] Infringement — In general (§120.01)

International issues — In general (§157.01)

Importation of drug product that was allegedly identified as useful through use of patented methods of screening substances for presence of active compounds does not infringe process patents under 35 U.S.C. §271(g), since patented processes were not used in actual synthesis of accused drug, in that identification and generation of data are not steps in manufacture of final drug product, and since drug that was identified as useful through patented process therefore is not product that was "made by" that process within meaning of Section 271(g); liability under Section 271(g) requires showing that patented process was used directly in manufacture of product, and not merely as predicate process to identify product to be manufactured.

Particular Patents

Particular patents — Chemical — Screening method

4,980,281, Housey, method of screening for protein inhibitors and activators, dismissal of infringement claim affirmed.

5,266,464, Housey, method of screening for protein inhibitors and activators, dismissal of infringement claim affirmed.

5,688,655, Housey, method of screening for protein inhibitors and activators, dismissal of infringement claim affirmed.

5,877,007, Housey, method of screening for protein inhibitors and activators, dismissal of infringement claim affirmed.

Case History and Disposition

Appeal from the U.S. District Court for the District of Delaware, Robinson, C.J.; 61 USPQ2d 1051.

Action by Bayer AG and Bayer Corp. against Housey Pharmaceuticals Inc. for declaratory judgment that defendant's patents are invalid, unenforceable, and not infringed, in which defendant counterclaimed, alleging infringement of its patents under 35 U.S.C. §271(g). Defendant appeals from dismissal of infringement counterclaim under Fed. R. Civ. P. 12(b)(6). Affirmed.

Attorneys:

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Judge:

Before Mayer, chief judge, and Dyk and Prost, circuit judges.

Opinion Text

Opinion By:

Dyk, J.

Housey Pharmaceuticals, Inc. ("Housey") appeals from the judgement of the United States District Court for the District of Deleware dismissing its counterclaim for infringement of United States Patent Nos. 4,980,281, 5,266,464, 5,688,655, and 5,877,007 for failure to state a claim. Because we conclude that infringement under 35 U.S.C. §271(g) is limited to physical goods that were manufactured and does not include information generated by a patented process, and because the physical goods here (drug products) were not "manufactured"by a process claimed in the asserted patents, we affirm the dismissal of Housey's infringement claims.

BACKGROUND

Housey is the assignee of U.S. Patents Nos. 4,980,281, 5,266,464, 5,688,655, and 5,877,007 (collectively "the Housey patents"), all entitled "Method of Screening for Protein Inhibitors and Activators." 1 The patents are directed to "a method of screening for substances which specifically inhibit or activate a particular protein affecting the cultural or morphological characteristics of the cell expressing the protein."U.S. Pat. No. 5,877,007 col. 1, ll. 18-21. The expression of the "particular protein" (referred to as the "protein of interest") results in a change in one or more identifiable characteristics of the cells expressing it. According to the disclosed and claimed method, a cell line is produced that is characterized by a higher production of the protein of interest relative to an original cell line. By applying substances ("agents") to both cell lines, it is possible to determine whether the agent is an activator or inhibitor of protein activity.2 Thus, for example, if a link between a protein and a disease is discovered, the disclosed method provides a process for identifying the effect that different agents have on the activity of the suspect protein.

On March 6, 2001, Bayer AG and Bayer Corporation ("Bayer") filed a complaint seeking declaratory judgment of invalidity, unenforceability, and non-infringement of the Housey patents. On March 27, 2001, Housey filed an answer to the complaint and asserted

a counterclaim for infringement of the Housey patents. The counterclaim alleged that Bayer "directly infringed claims of each of the patents-in-suit" and "contributed to infringement or induced others to infringe the patents-in-suit."(Answer to Complaint and Counterclaim at 4). Additionally, Housey alleged that Bayer "infringed the

method claims of the patents in suit pursuant to 35 U.S.C. Sec. 271(g)." *Id.* at 5. The factual basis of Housey's infringement claim as stated in the counterclaim was that:

> Pursuant to 35 U.S.C. §295, this Court may presume that a product was made [by Housey's] patented methods where there is a substantial likelihood that it was so made by and [Housey] has made reasonable efforts to determine the process actually used. Here, there is substantial likelihood that [Housey's] methods were used by Bayer to make the characterization of a pharmacologically active agent. Further, [Housey] has requested the defendants to identify the methods used in its facilities, but the [sic] Bayer has failed to do so. [Housey] has made the required reasonable efforts.

Id. at 4-5.

On April 16, 2001, Bayer filed a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure with respect to Housey's counterclaim for infringement under § 271(g), arguing that the provision "applies only to methods of manufacture, and does not apply to [Housey's] method patent claims ...[which] cover methods of use, not methods of manufacturing." (Pls.' Br. In Supp. Of their Mot. to Dismiss Infringement Claim Under 35 U.S.C. §271(g) at 2.). Bayer argued that "Section 271(g) is inapplicable as a matter of law and [Housey's] claim for infringement of its method claims under Section 271(g) should be dismissed." *Id.* Bayer characterized Housey's infringement allegations as follows:

> 1. Bayer is liable as an infringer when it sells in the United States a pharmaceutical composition containing a substance determined to be an inhibitor or activator of a target protein by use either in the United States or abroad of the [Housey] United States patented methods.
> 2. Bayer AB is liable as an infringer when it imports into the United States research data or information obtained from using the [Housey] patented methods.

Id. at 4.

In its opposition to Bayer's motion to dismiss, Housey similarly described its counterclaim for infringement under §271(g) as comprising two separate claims, the first of which was directed to "*the critical information*, the identification and characterization of a drug, [which] is made by [the] patented process" and the second of which was directed to "*the drug* made by [the] patented process." (ICT's Opp'n to Bayer's Mot. to Dismiss 35 U.S.C. 271(g) Claim at 2.). The parties, therefore, were in substantial agreement as to the scope of the counterclaim for infringement, characterizing it as extending to both the importation of a pharmaceutical composition identified by the patented process and the importation of information generated by the patented process.

The district court interpreted Housey's infringement claim under §271(g) to encompass:

> (1) [the sale] in the United States [of] a drug that was determined to be an inhibitor or activator of a target protein using the patented methods; and
> (2) import[ation] into or use in the United States [of] knowledge and information reflecting the identification or characterization of a drug acquired from using the patented methods.

Bayer AG v. Housey Pharm., Inc., 169 F.Supp.2d 328, 329 [61 USPQ2d 1051] (D. Del. 2001). Based on this interpretation, the court dismissed Housey's claim for infringement under §271(g) for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure. The court concluded that "[u]pon a plain reading of the statute, ... Section 271(g) addresses only products derived from patented *manufacturing processes*, i.e., methods of actually making or creating a product as opposed to methods of gathering information about, or identifying, a substance worthy of further development." *Id.* at 330. On August 12, 2002, the court entered final judgment under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Bayer on Housey's section 271(g) counterclaims. Housey timely appealed. We have jurisdiction pursuant to 28 U.S.C. §1295(a)(1). 3

DISCUSSION

We review issues of statutory construction without deference. *Doyon, Ltd. v. United States*, 214 F.3d 1309, 1314 (Fed. Cir. 2000). We review the grant of a motion to dismiss under Rule 12(b)(6) by applying the procedural law of the regional circuit. *C&F Packing Co., Inc. v. IBP, Inc.*, 224 F.3d 1296, 1306 [55 USPQ2d 1865] (Fed. Cir. 2000).

I

This case presents questions concerning the interpretation of §271(g), which provides:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States *a product which is made by a process patented* in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent .... A *product which is made by a patented process* will, for purposes of this title, not be considered to be so made after–
>
> (1) it is materially changed by subsequent processes; or
>
> (2) it becomes a trivial and nonessential component of another product.

35 U.S.C. §271(g) (2000) (emphases added). We are concerned here in particular with the meaning of the phrase "a product which is made by a [patented] process."We have construed portions of this statute in a number of previous cases. *See, e.g., Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 1318 [58 USPQ2d 1891] (Fed. Cir. 2001). However, this case presents issues not previously addressed. When interpreting statutory language, "words of a statute [are given] their 'ordinary, contemporary, common meaning,' absent an indication Congress intended them to bear some different import." *Williams v. Taylor*, 529 U.S. 420, 431 (2000) (citations omitted). Dictionaries of the English language provide the ordinary meaning of words used in statutes. *See, e.g., Carey v. Saffold*, 536 U.S. 214, 219-220 (2002).

II

Housey offers two theories as to why section 271(g) is applicable here. First, it contends that the information produced by Bayer using the patented processes claimed in the Housey patents is itself a product made by a patented process. Bayer, in turn, argues that (1) the word "made" means "manufactured"and that (2) information is not a manufactured product. There is no serious dispute between the parties concerning the second of these two propositions: if only products that have been "manufactured" are within the scope of 35 U.S.C. § 271(g), it necessarily follows that the statute applies only to physical goods and that information is not included. *Webster's Third New International Dictionary* ("*Webster's*") defines the verb form of "manufacture" as "to make (as raw material) into a product suitable for use ... to make from raw materials by hand or by machinery." *Webster's* at 1378 (1968). Similarly, *Random House Webster's Unabridged Dictionary* ("*Random House*") defines "manufacture" as "the making of *goods or wares* by manual labor or by machinery." *Random House* at 1172 (2d ed. 1998) (emphasis added).4 These definitions are consistent in referring to tangible objects and not intangibles such as information. Thus, the production of information is not within the scope of processes of "manufacture." *See Webster's* at 1378; *Random House* at 1172; *see also Diamond v. Chakrabarty*, 447 U.S. 303, 308 [206 USPQ 193] (1980). Housey, in fact, does not argue that information is within the statute if the term "made"is construed to mean "manufactured." (Appellant's Br. at 11-14.) We thus turn to the central question – whether the statutory term "made"means "manufactured."

III

As used in the statute, the term "made" is the past tense of the verb "make."The dictionaries offer multiple definitions of the term "make."Some definitions are limited to manufacturing, for example, "to bring (a material thing) into being by forming, shaping, or altering material: FASHION, MANUFACTURE." *Webster's* at 1363.5 Other definitions broadly encompass activities in addition to manufacturing. For example, Webster's defines "make" as "form as a result of calculation or design." *Id.*6 Under these circumstances the text is ambiguous, and we must look beyond the particular language being construed.

[1] In order to resolve the ambiguity in the statutory language, we look first to other provisions of the statute. *See Pollard v. E. I. du Pont de Nemours & Co.*, 532 U.S. 843, 852 (2001); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n.*, 505 U.S. 88, 98, (1992). In a related section of the Omnibus Trade and Competitiveness Act of 1988 (which added 35 U.S.C. §271(g)), the Act describes a person that uses a patented process to "produce" a product as a "manufacturer." 7 35 U.S.C. §287(b)(3)(B)(iii) (2000). Similarly, section 287(b)(4)(A) refers to "a person then engaged in the manufacture of a product" as a person that makes the product. By referring to the party that produces a product as a "manufacturer"and the maker as a "person engaged in the manufacture of a product", the statute clearly contemplates that "made" means "manufactured."

There are other indications as well that the statute is concerned exclusively with products that are physical goods produced by a manufacturing process. One statutory exception to section 271(g) rules out infringement where the allegedly infringing product "is materially changed by subsequent processes."35 U.S.C. §271(g)(1) (2000). Housey's position – that information itself is a "product" – is difficult to reconcile with the existence of this exception, which appears to contemplate a change in a physical product. Similarly, the second exception to section 271(g), which provides that there is no infringement where the accused product "becomes a trivial and nonessential component of another product," also appears to contemplate a physical product.

However, Housey urges that the use of the term "manufacture" in 35 U.S.C. §101 suggests that "made by" as used in section 271(g) should not be limited to methods of "manufacture." Section 101 defines the scope of patentable subject matter as including "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. §101 (2000). Housey's theory is that Congress used the word "manufacture" when it wished to refer to manufacturing, and therefore, must have intended a different meaning when using the phrase "made by." We do not agree. We first note that the usage of "manufacture" in section 101 as cited by Housey is the noun form of the word and not the verb form. Thus, Housey has pointed to no provision in the Patent Act where Congress used the term "manufacture"to denote the process of manufacturing. In any event, the Supreme Court has said, "Congress, needless to say, is permitted to use synonyms in a statute." *Tyler v. Cain*, 533 U.S. 656, 664 (2001) (interpreting the statutory language "made" as synonymous with "held"); *See also, e.g. Davis v. United States*, 495 U.S. 472, 481 (1990) (holding that the statutory language "for the use of" is synonymous with "in trust"). Housey's position suggests an unrealistic level of clarity in congressional word selection. We see nothing in section 101 that suggests that "made" in section 271(g) should be construed to be broader than "manufacture." 8

IV

The legislative history leads to the same conclusion: that Congress was concerned solely with physical goods

that had undergone manufacture.

The history of the enactment of the Process Patents Amendments Act is quite long. *See Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1574 [38 USPQ2d 1705] (Fed. Cir. 1996). Section 271(g) was not enacted on an entirely blank slate. Rather, it was designed to provide new remedies to supplement existing remedies available from the International Trade Commission ("ITC") under 19 U.S.C. §1337 (2000). *See* H.R. Rep. No. 100-60 at 8-9. Section 1337 (Section 337 of the Tariff Act of 1930) defines "[u]nfair methods of competition" in import trade. 19 U.S.C. §1337(a)(1)(A) (2000). One of these statutory "unfair methods of competition" is the "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that ... are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." 19 U.S.C. §1337(a)(1)(B); *see also* 19 U.S.C. §1337(a)(1)(A) (referring to "unfair acts in the importation of articles"). When enacting §271(g), Congress recognized the availability of redress from the ITC, but noted that the remedies available thereunder were insufficient to fully protect the owners of process patents. H.R. Rep. No. 100-60 at 8-9. Thus, the legislative history suggests that section 271(g) was intended to address the same "articles"as were addressed by section 1337, but to add additional rights against importers of such "articles." 9

Even if the legislative history did not affirmatively suggest an intent to limit coverage to manufactured "articles" in accordance with section 1337, we have been directed to nothing in the legislative history suggesting that Congress was concerned that the preexisting statutory scheme failed to reach intangible information, or that the substantive coverage of the Act, as opposed to the available remedies, was to be expanded. Each and every reference to the provision that became section 271(g) describes it as directed to manufacturing.

For example, a provision similar to section 271(g) as enacted was proposed as part of an earlier bill in both the House of Representatives and the Senate in 1983. H.R. 4526, 98th Cong. §1 (1983); S. 1535, 98th Cong. §1 (1983). Two new acts of infringement were to be created by the proposed legislation: 1) infringement by importation, sale, or use "of a product made in another country by a process patented in the United States" (the precursor to section 271(g)); and 2) infringement by supplying "the material components of a patented invention ... intending that such components will be combined outside the United States" (the provision that became section 271(f)). *Id.* The second new act of infringement was a response to the Supreme Court's decision in *Deepsouth Packing Co., Inc. v. Laitram Corp.*, 406 U.S. 518 [173 USPQ 769] (1972), which held that the intentional exportation of components to be combined into a patented article was not an act of infringement. 130 Cong. Rec. 28,069 (1984). Together, the two new statutory acts of infringement were intended "to avoid encouraging *manufacturing* outside the United States." 10 *Id.* (emphasis added.)

A subsequent bill in the following year again proposed a precursor of section 271(g): "[i]f the patent invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor a product produced by such process infringes the patent." S. Rep. No. 98-663 at 30 (1984) (discussing S. 1535, 98th Cong. §2 (1984)). According to the Senate Report, a principal aim of S. 1535 was "[t]o declare it to be patent infringement to import into, or to use or sell in the United States, a product *manufactured by a patented process*." *Id.* at 1 (emphasis added).

Again in 1986, language was proposed substantially similar to section 271(g) as it now

exists. H.R. Rep. No. 99-807, at 1-2 (1986).11 The House report reasoned that:

> The failure of American patent law to make unlawful the *importation of goods made using an American process patent* has deep historical roots. American patent law – like the law of other nations –does not have an extraterritorial effect .... With respect to process patents, courts have reasoned that the only act of infringement is the act of making through the use of a patented process; therefore, there can be no infringement if that act occurs outside the United States. Although the courts are correctly construing current law, this rationale is inadequate public policy because it ignores the reality that the offending act is the importation of a product made through the use of a protected process patent or its subsequent sale within the United States.

Id. at 5 (emphasis added). Here, the report equates products with physical "goods."

A 1987 Senate report on substantially identical legislation also supports limiting the statute to manufactured tangible products. According to the report "[t]he primary target of the U.S. process patentholder will naturally be *the manufacturer, who is practicing the process and importing the resulting goods into the United States*." S. Rep. No. 100-83, at 39 (1987) (emphasis added). In discussing potential infringers, the report stated that "three types of infringers" were envisioned:

> (1) *[t]he manufacturer* ... (2) [a]n infringing importer, user or seller who had knowledge before the infringement that a patented process was used *by the manufacturer to make the product* ... (3) [a]n innocent (i.e. unknowing) infringing retailer or importer, user or seller who does not himself use the process, [and] is entitled to take advantage of the limitations on damages and other remedies available.

Id. at 40 (emphasis added). The "manufacturer" was referred to as the "preferred defendant because of its direct knowledge of the process." *Id.* at 39. The proposed statute also permitted suit against "the persons receiving the goods in this country in the belief that they may be in the best position, apart from the manufacturer, to determine *how the goods were made*." *Id.* (emphasis added). Here again, there is no indication of any intent to reach products other than tangible products produced by manufacturing processes.

Housey urges that section 271(g) was enacted "to provide protection to process patent owners which is *meaningful and not easily evaded*."(Appellee's Br. at 15) (citing H.R. Rep. No. 100-60 at 13). However, this broadly stated purpose hardly suggests that the statute covers information. A similar statement was made earlier in the report as follows:

> The purpose of this bill is to provide meaningful protection to owners of patented processes. Under current patent law, owners of such patents have remedies for unauthorized use of the process only if the process was used in the United States. As a consequence, while a *domestic manufacturer* using the patented process would infringe the process patent, a *foreign manufacturer* who imports the product would not.

H.R. Rep. No. 100-60 at 3. This passage clearly reflects concern over competition between domestic and foreign *manufacturers*. The report further provides:

> *The value of new manufacturing techniques is reflected in the resulting new products*. A new process may enhance the quality of the product produced, or the new process may permit the product to be made much more economically. In some cases, for example biotechnology, the new process may be the only method of producing a new product. In all of these instances, the advantage to the process patent owner is realized by suing or selling the product, or licensing others to do so. As a consequence, the unfettered ability of others to import, sell or use a product

made by the patented process, severely diminishes the value of a U.S. process patent. *Id.* Thus, Congress was concerned with tangible products and not mere information. Here again, "process patent" was interpreted as synonymous with "manufacturing technique."

In the face of silence in the legislative history, here as to the coverage beyond manufactured articles, courts are reluctant to broadly interpret the legislation. *See Dewsnup v. Timm*, 502 U.S. 410, 419 (1992) (stating that "th[e] Court has been reluctant to accept arguments that would interpret the [Bankruptcy] Code, however vague the particular language under consideration might be, to effect a major change in pre-Code practice that is not the subject of at least some discussion in the legislative history"); *Sheet Metal Workers' Int'l Ass'n v. Lynn*, 488 U.S. 347, 356 (1989) (reasoning that "had Congress contemplated such a result, we would expect to find some discussion of it in the text of the [Act] or its legislative history"); *Shearson/American Express, Inc. v. McMahon*, 482 U.S. 220, 238 (1987) (refusing to adopt an interpretation of a statute, in part, because "[t]here is no hint in these legislative debates that Congress intended [that result]"). The legislative history's very silence thus suggests that Congress did not intend to expand coverage beyond manufactured articles.

V

Finally, reading the statute to cover processes other than manufacturing processes could lead to anomalous results. The importation of information in the abstract (here, the knowledge that a substance possesses a particular quality) cannot be easily controlled. As Bayer points out, a person possessing the allegedly infringing information could, under Housey's interpretation, possibly infringe by merely entering the country. (Appellee's Br. at 39.) Such an illogical result cannot have been intended. *See Paul v. Davis*, 424 U.S. 693, 698-99 (1976).

Under these circumstances we think it is best to leave to Congress the task of expanding the statute if we are wrong in our interpretation. Congress is in a far better position to draw the lines that must be drawn if the product of intellectual processes rather than manufacturing processes are to be included within the statute.

We, therefore, hold that in order for a product to have been "made by a process patented in the United States" it must have been a physical article that was "manufactured" and that the production of information is not covered.

VI

This, however, is not the end of the inquiry. As characterized by Bayer in its motion to dismiss, Housey's counterclaim of infringement also extended to "a pharmaceutical composition containing a substance determined to be an inhibitor or activator of a target protein by use either in the United States or abroad of the [Housey] United States patented methods." (Pls.' Brief in Supp. Of their Mot. to Dismiss Infringement Claim Under 35 U.S.C. § 271(g) at 4.) In opposing dismissal, Housey agreed that the counterclaim included drug products, stating that "*the drug* [itself was] made by [the] patented process." (ICT's Opp'n to Bayer's Mot. to Dismiss 35 U.S.C. §271(g) Claim at 2.) The factual basis upon which Housey made its counterclaim for infringement by the drug product was that:

> Pursuant to 35 U.S.C. §295, [the district court] may presume that a product was made [by Housey's] patented methods where there is a substantial likelihood that it was so made by and [Housey] has made reasonable efforts to determine the process actually used. Here, there is substantial likelihood that [Housey's] methods were used by Bayer to make the characterization of a pharmacologically active agent.

(Answer to Complaint and Counterclaim at 4-5.) Thus, Housey alleged that, as a result of the claimed research process, Bayer produced drugs using information created by the patented processes.

[2] It is beyond dispute that a drug is a physical product that has been manufactured. The issue, therefore, is the necessary relationship under the statute between the "process patented in the United States"and the resulting product; *i.e.*, we must determine whether a drug that was identified as useful through the use of a patented process is a "product which [was] *made by* [that] process." 35 U.S.C. §271(g) (2000). As we have previously noted:

[t]he statute [35 U.S.C. §271(g)] does not specify what products will be considered to

have been 'made by' the patented process, apparently because Congress wanted the courts to resolve this critical question of proximity to the product of the patented process on a case-by-case basis. *Bio-Technology General Corp. v. Genetech, Inc.*, 80 F.3d 1553, 1561 [38 USPQ2d 1321] (Fed. Cir. 1996). In *Bio-Technology* we affirmed the district court's ruling that a protein made by a host organism expressing an inserted plasmid was a product "made by" the patented process for creating the plasmid itself. *Id.* Here, unlike the process in *Bio-Technology*, the patented process is not used in the actual synthesis of the drug product. We agree with the district court's conclusion that "processes of identification and generation of data are not steps in the manufacture of a final drug product." *Bayer AG*, 169 F.Supp.2d at 331.

The statute requires that the allegedly infringing product have been "made *by* a process patented in the United States." 35 U.S.C. §271(g) (emphasis added). The pertinent dictionary definitions of "by"are "through the means or instrumentality of[;] ... through the direct agency of[;] ... through the medium of[;] ... through the work or operation of." *Webster's* at 307.12 Thus, the process must be used directly in the manufacture of the product, and not merely as a predicate process to identify the product to be manufactured. A drug product, the characteristics of which were studied using the claimed research processes, therefore, is not a product "made by" those claimed processes. Accordingly, Housey did not state a claim of infringement by a Bayer drug product based on its asserted method claims.

CONCLUSION

For the foregoing reasons, the decision of the district court to dismiss Housey's claims of infringement under 35 U.S.C. §271(g) is

AFFIRMED

COSTS

No costs.

Footnotes

1 All four Housey patents claim priority from U.S. Application No. 154,206 filed February 10, 1988, although the final three patents included additional disclosure via a continuation-in-part application filed August 10, 1989. For purposes of this appeal the patents are identical in all material aspects, and so will be described with respect to the final issued patent, U.S. Patent No. 5,877,007 ("the '007 patent").

2 Claim 1 of U.S. Patent No. 4,980,281 is exemplary of the claims at issue, and provides in its entirety:

A method of determining whether a substance is an inhibitor or activator of a protein whose production by a cell evokes a responsive change in a phenotypic characteristic other than the level of said protein in said cell per se, which comprises:

(a) providing a first cell line which produces said protein and exhibits said phenotypic response to the protein;

(b) providing a second cell line which produces the protein at a lower level than the first cell line, or does not produces the protein at all, and which exhibits said phenotypic response to the protein to a lesser degree or not at all;

(c) incubating the substance with the first and second cell lines; and

(d) comparing the phenotypic response of the first cell line to the substance with the phenotypic response of the second cell line to the substance.

3 Amici Affimetrix, Inc., Perlegen Sciences, Inc., and Symyx Technologies, Inc. stated that subsequently, on November 21, 2002, the district court entered judgment that all of the asserted claims of the patents-in-suit are invalid. Based on this holding, the amici urge that this appeal had become moot. The validity decision of the district court is separately subject to appeal and, in fact, is on appeal to this court in a related case. Housey Pharmaceuticals, Inc. v. Astrazeneca UK Ltd., No. 03-1193, -1210 (Fed. Cir. filed Jan. 10, 2003). Therefore, the district court's invalidity decision does not render this case moot.

4 In American Fruit Growers, Inc. v. Brogdex Co., the Supreme Court defined the verb form of "manufacture" as "*the production of articles* for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." 283 U.S. 1, 11 (1931) (quoting the *Century Dictionary*). An "article" is "one of a class of *material things ... piece of goods*: COMMODITY." *Webster's* at 123 (emphasis added).

5 Random House states: "to bring into existence by shaping or changing material, combining parts, etc." *Random House* at 1161.

6 Random House states: "to produce; cause to exist or happen; bring about." *Random House* at 1161.

7 By sending a request for information to the "person then engaged in the manufacture of the product" to determine the process used, an alleged infringer can limit potential damages under section 271(g). 35 U.S.C. § 287(b).

8 Appellant additionally cites 35 U.S.C. §100(b), which defines the term "process"as "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." This definition, however, does not aid in construing the proper scope of the language "made by" in section 271(g).

9 We recognize that section 1337 covers both articles that were "made" and articles that were "produced, processed, or mined." While this language in section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g).

10 The precursor language to section 271(g) was subsequently deleted from the Senate version of the legislation so that issues regarding its scope could be addressed. 130 Cong. Rec. 31,834 (statement of Sen. Mathias). The remaining sections of the bill became the Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3833.

11 The proposed language for §271(g) provided:

Whoever without authority imports into the United States or sells or uses within the United States a product which is *made by a process patented* in the United States shall be liable as an infringer, if the importation, sale, or use of

the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the use of a product unless there is no adequate remedy under this title for infringement on account of the importation or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after —

(1) it is materially changed by subsequent processes; or

(2) it becomes a minor or nonessential component of another product. H.R. Rep. No. 99-807, at 1-2 (1986) (emphasis added).

12 Random House similarly defines "by" as "through the agency, efficacy, work, participation, or authority of." *Random House* at 287.

- End of Case -

